GUIDANT

Physician's Manual

ENDOTAK® RELIANCE™
Models 0147/0148/0149

ENDOTAK® RELIANCE™ S
Models 0127/0128/0129

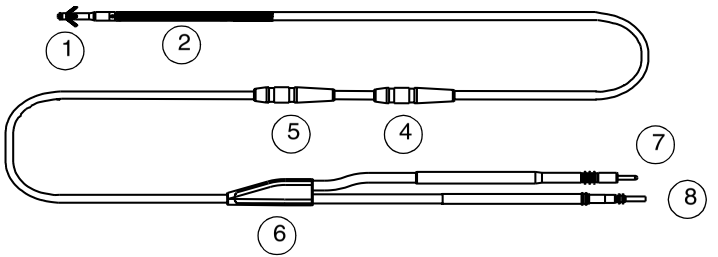
Steroid-Eluting
Tined Endocardial
Defibrillation Leads

CARDIAC

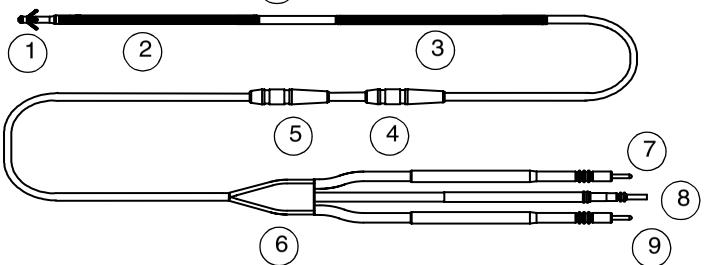
RHYTHM

MANAGEMENT

RESTRICTED DEVICE: Federal law (USA) restricts the sale, distribution, or use of this device to, by, or on the lawful order of a physician.



ENDOTAK RELIANCE S Leads
Models 0127/0128/0129



ENDOTAK RELIANCE Leads
Models 0147/0148/0149

1. Distal steroid-eluting pace/sense electrode (cathode)
2. Proximal pace/sense spring electrode (anode), distal defibrillating spring electrode
3. Proximal defibrillating spring electrode–ENDOTAK RELIANCE only
4. Suture Sleeve
5. Second Suture Sleeve–Models 0129 and 0149 only
6. Yoke
7. Distal defibrillating electrode terminal (cathode)
8. Pace/sense electrode terminal
9. Proximal defibrillating electrode terminal (anode)

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INFORMATION FOR USE

Device Description

The ENDOTAK® RELIANCE™ lead, Models 0147/0148/0149, and the ENDOTAK® RELIANCE™ S lead, Models 0127/0128/0129, are steroid-eluting, tined, endocardial cardioversion/defibrillation and pace/sense leads. The ENDOTAK RELIANCE lead (dual coil) and the ENDOTAK RELIANCE S lead (single coil) are for use as an integral part of an AICD automatic implantable cardioverter defibrillator system with DF-1[1] and IS-1[2] ports. The lead features a small active surface area of the distal tip electrode that is designed to increase pacing impedance.

Instructions in this manual should be used in conjunction with other resource material including the applicable AICD device system manual, and if used, the applicable VENTAK® External Cardioverter Defibrillator (ECD) user's manual, the ENDOTAK SQ lead array family physician's manuals and the AICD Y Connector product data sheet.

Indications

The ENDOTAK RELIANCE lead, Models 0147/0148/0149, and the ENDOTAK RELIANCE S lead, Models 0127/0128/0129, provide pacing and rate-sensing and deliver cardioversion and defibrillation shocks for AICD automatic implantable cardioverter defibrillator systems.

Contraindications

Use of the ENDOTAK RELIANCE or ENDOTAK RELIANCE S lead is contraindicated for the following patients:

- Patients who have a unipolar pacemaker
- Patients with a hypersensitivity to a single dose of approximately 1.0 mg of dexamethasone sodium phosphate
- Patients with tricuspid valvular disease
- Patients with mechanical tricuspid heart valves

Warnings

In the following list of warnings, page numbers are indicated for those warnings that are specific to other areas of the man-

ual. Refer to the indicated pages for information relevant to the warning.

AICD/Lead Compatibility

- Do not attempt to use the ENDOTAK lead system with any device other than a commercially available implantable defibrillator system with which it has been tested and demonstrated to be safe and effective. The potential adverse consequences of using a combination that has not been tested and demonstrated to be safe and effective may include, but are not limited to, undersensing cardiac activity and failure to deliver necessary therapy.

Implanting

- Lead fracture, dislodgment, abrasion and/or an incomplete connection can cause a periodic or continual loss of rate-sensing, possibly resulting in arrhythmia nondetection; or over-sensing of rate, possibly resulting in inappropriate delivery of a pulse generator shock; or inadequate delivery of conversion energy.
- Although pliable, the lead body is not designed to tolerate excessive flexing, bending, or tension. This could cause structural weaknesses, conductor discontinuity, and/or lead dislodgment. (Page 14)
- Take care to obtain appropriate electrode position. Failure to do so may result in higher defibrillation thresholds or may render the lead unable to defibrillate a patient whose tachyarrhythmia(s) might otherwise be convertible by an AICD system. (Page 19)
- In order to deliver defibrillation therapy, the single-coil ENDOTAK RELIANCE S lead must be implanted with a separate defibrillation electrode. Guidant recommends using the ENDOTAK RELIANCE S lead with a pectorally implanted device that uses the metallic housing as a defibrillation electrode. (Page 19)

Electrical Performance

- When connecting the lead to ECD cables, and/or later to the AICD pulse generator, it is very important that proper connections are made. Damage to the heart could result if a high-voltage defibrillating pulse were to be delivered through the pace/sense porous tip electrode. (Page 21)

Conversion Testing

- Use of any component of the ENDOTAK lead system to assist in delivery of external-source rescue shocks could cause extensive tissue damage. (Page 24)

Securing and Tunneling

- Do not kink, twist, or braid the lead terminals as doing so could cause lead insulation abrasion damage. (Page 26)

Precautions

General

- The lead and its accessories are intended for one-time use only. Do not reuse.
- It has not been determined whether the warnings, precautions, or complications usually associated with injectable dexamethasone sodium phosphate apply to the use of the low concentration, highly localized, controlled-release device. For a listing of potentially adverse effects, refer to the *Physician's Desk Reference*.
- Refer to the Implant Information, Implantation, and Post-Implant Evaluation sections of this manual for cautions specific to handling, implanting, and testing the ENDOTAK RELIANCE lead family. Failure to observe these cautions could result in incorrect lead implantation, lead damage, and/or harm to the patient.

Adverse Events

Given the similar design features, including the porous tip electrode, steroid elution, and high pacing impedance, the ENDOTAK ENDURANCE Rx clinical investigation was used to support the ENDOTAK RELIANCE or ENDOTAK RELIANCE S lead. The following are the adverse events reported in that investigational study.

A total of two complications and six observations related to the implanted device or system components were reported during the clinical investigation of the ENDOTAK ENDURANCE Rx lead. One hundred and one patients were enrolled in the investigation, and ninety-eight were implanted with 478.6 cumulative implant months.

Observed Adverse Events

Table 1 reports lead or system related complications and observations for the ENDOTAK ENDURANCE Rx lead.

Table 1. ENDOTAK ENDURANCE Rx lead Study Complications and Observations

	# of pts (n = 98)	% of pts (95% CI)	# of leads (n = 98)	# of AEs[a]
Complications [b] (all types)	**2**	**2.0% (0.0–4.8%)**	**2**	**2**
Hematoma	1	1.0% (0.0–3.0%)	1	1
Noncapture (connector)	1	1.0% (0.0–3.0%)	1	1
Observations[c] (Type I)	**6**	**6.0% (1.3–10.7%)**	**6**	**6**
Oversensing	2	2.0% (0.0–4.8%)	2	2
Threshold difficulty	2	2.0% (0.0–4.8%)	2	2
Telemetry	1	1.0% (0.0–3.0%)	1	1
Inappropriate therapy	1	1.0% (0.0–3.0%)	1	1

a. AE = Adverse Event is defined as the total (lead related) complications and observations.
b. Complications are defined as adverse events requiring invasive measures to correct (eg, surgical intervention).
c. Observations are defined as adverse events which are correctable by non-invasive measures (eg, reprogramming); Type 1 observations are related to the implanted device or a system component.

Potential Adverse Events

Based on the literature and lead implant experience, the possible physical effects from implantation of an ENDOTAK RELIANCE or ENDOTAK RELIANCE S lead are listed below in alphabetical order:

- Air embolism
- Allergic reaction
- Bleeding
- Cardiac perforation
- Chronic nerve damage
- Displacement/dislodgment
- Erosion/extrusion
- Local tissue reaction
- Low amplitude VF signals
- Myocardial injury
- Lead fracture, insulation break
- Lead tip deformation and/or breakage
- Myocardial irritability
- Pneumothorax

- Fibrotic tissue formation
- Hematoma
- Inappropriate therapy
- Incomplete connection with pulse generator
- Infection
- Keloid formation
- Lead abrasion
- Post-shock rhythm disturbances
- Random component failures
- Shunting of current or insulation of myocardium during defibrillation with internal or external paddles
- Transvenous lead-related thrombosis
- Threshold elevation
- Venous occlusion
- Venous perforation

Clinical Trial

Given the similar design features, including the porous tip electrode, steroid elution, and high pacing impedance, the ENDOTAK ENDURANCE Rx clinical investigation was used to support the ENDOTAK RELIANCE or ENDOTAK RELIANCE S lead. The following is a summary of findings from the ENDOTAK ENDURANCE Rx Lead Clinical Investigation.

Clinical Investigation

The study was a non-randomized historical control study comparing the performance of the ENDOTAK ENDURANCE Rx lead to that of the ENDOTAK DSP lead. The objectives of this investigation were to demonstrate higher pacing impedance and lower pacing threshold performance of the ENDOTAK ENDURANCE Rx lead compared to the historical control lead, the ENDOTAK DSP. Ninety-eight patients were implanted with the ENDOTAK ENDURANCE Rx lead. The mean implant duration of the study population was 4.9 months with a cumulative implant duration of 478.6 months. No statistical differences were found in the baseline variables between the study patient group and the historical control group with respect to demographic profiles except for age, primary arrhythmia and antiarrhythmic drug therapy. None of these factors are clinically significant relative to meeting the study endpoints. Additional demographic information is presented in Table 2.

Table 2. Description of the Study Population (n = 98)

Characteristic	ENDOTAK ENDURANCE Rx Lead Population	ENDOTAK DSP Lead Population
Number of Patients	98	78
Gender		
Male	78	60
Female	20	18
Age at Implant (years)		
Range	29.8–84.7	33–75
Mean ± Standard Deviation	66 ± 11.4	60.9 ± 9.7
Mean LVEF ± Standard Deviation (%)	34.3 ± 13.4	35.1 ± 14.1
Primary Arrhythmia		
MVT	68	38
VF	17	27
PVT	8	5
Other	5	8
Primary Cardiac Disease		
Coronary artery disease	62	42
Cardiomyopathy	25	26
Other	11	10

Lead measurements were recorded at implant, predischarge, 1 month, and 3 month follow-up visits. The results in Table 3 and Table 4 show a statistically significant difference in impedance and threshold values when comparing the ENDOTAK ENDURANCE Rx lead and the control lead.

Table 3. Lead Pacing Impedance by Follow-up Period (n = 98)

Follow-up	ENDOTAK ENDURANCE Rx			ENDOTAK DSP			Statistical Analysis		% Change
	Mean (Ω)	SD	N	Mean	SD	N	t-test	P-Value	
Implant	906.0	180.8	96	535.7	111.7	77	15.7	0.0001[a]	69.1
Predis-charge	815.5	142.5	95	520.0	86.3	67	15.1	0.0001[a]	56.8
1 month	830.1	118.7	88	604.2	111.5	58	11.5	0.0001[a]	37.4
3 months	836.5	130.7	79	635.5	90.1	26	7.3	0.0001[a]	31.6

a. Extremely statistically significant ($p \leq 0.001$).

The mean ENDOTAK ENDURANCE Rx lead impedance was 69.1% higher at implant and 31.6% higher at 3 months than the control lead. Subsequently, the mean ENDOTAK ENDURANCE Rx lead impedance is 67% above the nominal industry standard of 500 Ω at 3 months. Figure 1 shows a graphical comparison of ENDOTAK ENDURANCE Rx lead, the control lead, and the nominal industry standard in terms of lead impedance.

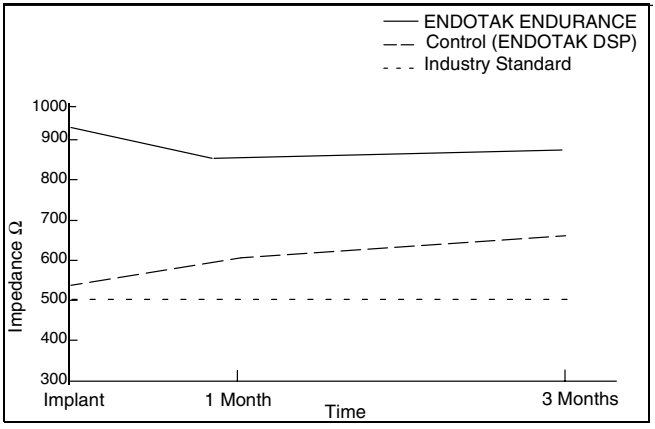


Figure 1. ENDOTAK ENDURANCE Rx lead impedance by follow-up period. (n=98)

Pacing thresholds measured at implant, predischarge, 1 month and 3 month follow-up visits were compared to the historical control to demonstrate lower pacing threshold performance. Study results in Table 4 show that the ENDOTAK ENDURANCE Rx lead pacing threshold was 37.1% lower at implant and 42.9% lower at 3 months when compared to the control lead representing a statistically significant reduction in pacing thresholds throughout the chronic implant period.

Note: *The data in Table 4 was obtained using clinical leads that contained an average dose of 0.4 mg dexamethasone sodium phosphate, which is less than the approximate dose of 1.0 mg used in the commercially available design.*

R-wave amplitudes were also measured at implant and were compared to the implant R-wave amplitudes for the historical control to determine equivalency of sensing characteristics. Results demonstrate that the ENDOTAK ENDURANCE Rx lead's R-wave amplitudes are equivalent to those for the ENDOTAK DSP lead.

Table 4. Mean Pacing Threshold (V) at 5.0 ms by Follow-Up Period (n=98)

Follow-up	ENDOTAK ENDURANCE Rx			ENDOTAK DSP			Statistical Analysis		% Change
	Mean (Volts)	SD	N	Mean	SD	N	t-test	P-Value	
Implant	0.66	0.60	95	1.05	0.81	77	–3.63	0.0004[a]	–37.1
Predis-charge	0.63	0.29	95	1.27	1.08	67	–5.51	0.0001[a]	–50.4
1 month	0.76	0.48	88	1.52	0.93	58	–6.48	0.0001[a]	–50.0
3 months	0.88	0.74	79	1.54	0.77	25	–3.85	0.0002[a]	–42.9

a. Extremely statistically significant ($p \leq 0.001$).

There was no statistical difference in the number of patient deaths between the ENDOTAK ENDURANCE Rx lead and the control lead. There were two complications in the ENDOTAK ENDURANCE Rx lead study with one due to a header connector issue that was resolved by tightening the set screws, and the second due to a hematoma. One complication was documented in the historical control group during a three month duration that was due to infection. An actuarial analysis on the complications demonstrates no significant difference between the ENDOTAK ENDURANCE Rx lead and the Control lead with the p-value = 0.69.

ENDOTAK ENDURANCE Rx lead's higher impedance values and low pacing thresholds may combine to reduce pacing system energy requirements—potentially improving pacing system longevity. For specific pacing system longevity values, refer to the applicable pulse generator physician's manual.

Warranty

See the enclosed Lead Information card for warranty and guarantee information. For additional copies, please contact Guidant Corporation at the address on the back cover.

Refer to the Contraindications, Warnings, Precautions, and Adverse Events sections of this manual for information concerning the performance of this device.

DEVICE FEATURES

Detailed Device Description

Features of the ENDOTAK RELIANCE or ENDOTAK RELIANCE S lead include the following components:

- **Porous Tip Electrode:** The porous tip electrode serves as the cathode for intracardiac right ventricular electrogram rate-sensing and pacing. The lead uses a platinum-iridium porous tip electrode design that increases the effective active area for sensing by allowing fibrotic tissue ingrowth and an increase in chronic lead tip stability while maintaining a small surface area for pacing.
- **Steroid:** The tip electrode contains approximately 1.0 mg dexamethasone sodium phosphate contained in a silicone rubber binder. Upon exposure to body fluids, the steroid elutes from the electrode. Steroid suppresses the inflammatory response believed to cause threshold rises typically associated with implanted pacing electrodes. Lower thresholds are desirable because they can increase pacing safety margins and reduce pacing energy requirements.
- **High Pacing Impedance:** The lead features a small active surface area of the distal tip electrode that is designed to increase pacing impedance. The lead's high impedance performance and low pacing thresholds may combine to reduce pacing system energy requirements—potentially increasing the pacing longevity of the pulse generator.
- **Spring Electrodes:** The distal spring electrode is intended to serve as an anode for rate-sensing and pacing and as a cathode or anode for cardioversion/defibrillation shocks. The proximal spring electrode on the ENDOTAK RELIANCE lead is intended to serve as an anode or cathode for cardioversion/defibrillation shocks. The ENDOTAK RELIANCE S lead uses the implanted device's metallic housing as a defibrillation electrode.
- **Lead Body:** The isodiametric lead body contains one conductor for pacing/sensing. The ENDOTAK RELIANCE lead has two conductors for defibrillation and the ENDOTAK RELIANCE S lead has one conductor for defibrillation. The conductors are coated with PTFE and insulated in separate lumens within the silicone rubber lead body. A second layer of silicone coats the lead body providing additional insulation and uniform body diameter. Fixation tines, a terminal

yoke, suture sleeves, and terminal moldings are fabricated from molded silicone rubber. The entire lead body fits through a 9 Fr lead introducer when not retaining a guide wire. A color-coded mark on the terminal end of the lead allows for a quick visual reference of the lead length. The lead color matches the same length stylet cap color.

- **Lubricious Coating:** The ENDOTAK RELIANCE lead family is the first to introduce a proprietary coating that makes the silicone lead surface more lubricious. The coating reduces both the static and dynamic coefficients of friction, making the lead surface feel and handle like polyurethane while providing the time-tested reliability of silicone.
- **Terminals:** The ENDOTAK RELIANCE lead has three terminals: two DF-1 (shock), and one IS-1 bipolar (pace/sense). The ENDOTAK RELIANCE S lead has one DF-1 (shock) terminal and one IS-1 terminal (pace/sense).The pace/sense terminal is tubular and is fitted with a stylet guide to facilitate the insertion of a stylet.

The lead is intended for chronic implantation within the superior vena cava, right atrium, and right ventricle. When connected to the AICD pulse generator, the implanted lead will perform the following functions:

- Provide rate-sensing and shocking electrode electrograms
- Deliver cardioverting/defibrillating electrical shocks from the pulse generator to the heart
- Provide pacing capabilities if available in the AICD pulse generator

Nominal overall lengths of the leads are as follows:

ENDOTAK RELIANCE	**0147**	**0148**	**0149**
	59 cm	64 cm	90 cm
ENDOTAK RELIANCE S	**0127**	**0128**	**0129**
	59 cm	64 cm	90 cm

The electrode spacing (measured from the distal tip to distal end of the proximal spring electrode) of the ENDOTAK RELIANCE lead is 18 cm (Figure 2).

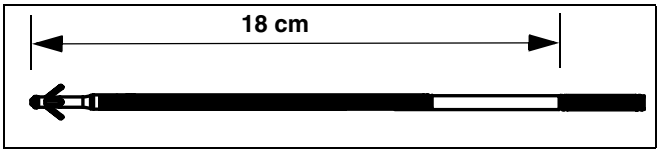


Figure 2. Electrode spacing for the ENDOTAK RELIANCE lead is measured from the distal tip to the distal end of the proximal spring electrode.

LEAD EVALUATION

Implant Information

Proper surgical procedures and techniques are the responsibility of the medical professional. The described implant procedures are furnished for informational purposes only. Each physician must apply the information in these instructions according to professional medical training and experience.

Use of the lead alone is the least invasive approach to AICD lead system implantation. In some cases, a lead from the ENDOTAK SQ array family may be implanted in conjunction with the ENDOTAK RELIANCE or ENDOTAK RELIANCE S lead in an attempt to convert a patient's tachyarrhythmia(s). Refer to the ENDOTAK SQ physician's manuals for alternative ENDOTAK lead system configurations.

A major consideration in choosing the ENDOTAK RELIANCE lead family is that it does not require a thoracotomy. The physician should weigh its advantages against the patient's ability to withstand additional electrophysiology (EP) testing (arrhythmia induction and conversion testing), and a possible thoracotomy should the lead system prove ineffective.

Various factors, such as cardiomegaly or drug therapy, may necessitate repositioning of the defibrillating leads or substitution of one lead system for another in order to facilitate arrhythmia conversion. **In some cases, reliable arrhythmia conversion may not be obtained with any leads at the available AICD energy levels.**

Bipolar pacemakers may be used with the ENDOTAK RELIANCE lead family and AICD pulse generator as long as the pacemaker and AICD pulse generator do not interact, causing AICD pulse generator nondetection or false detection. Refer to "Minimizing Pacemaker Interaction" (Page 19) for more information.

The lead is not designed, sold, or intended for use except as indicated.

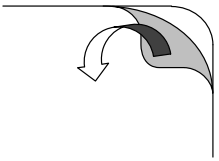
Included Items

The following items are packaged with the ENDOTAK RELIANCE or ENDOTAK RELIANCE S lead:

- Lead caps (2) DF-1 and (1) IS-1
- Vein pick
- Stylet guide
- Soft stylets (0.014-in/0.36-mm diameter)
- Firm stylets (0.016-in/0.41-mm diameter)
- Literature packet
- DF-1 port plugs (ENDOTAK RELIANCE S lead only)

Opening Instructions

The outer package and inner sterile tray may be opened by authorized personnel under clean conditions. To ensure sterility, the sealed inner sterile tray must be opened using accepted aseptic technique by scrubbed, masked, sterile-gowned personnel. The sterile tray is opened by peeling back the cover.



Sterilization

Guidant sterilizes the lead and accessories with ethylene oxide gas (EtO) before final packaging. When they are received, they are sterile and ready for use. If the container is wet, damaged, punctured, or if the seal is broken, return the lead to the nearest Guidant representative. Never attempt to resterilize the lead.

Surgical Preparation

Instrumentation for cardiac monitoring, imaging (fluoroscopy), defibrillation, and lead signal measurements must be available during implant. When using electrical instrumentation, electrically isolate the patient from potentially hazardous current leakage. Guidant also recommends availability of sterile duplicates of all implantable items in case of accidental damage or contamination.

Accessory Options

The following items are packaged with the lead and are also available from Guidant as accessory items:

Suture Sleeves

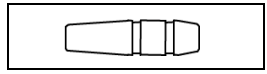


Figure 3. The long tapered end of the suture sleeve faces toward the vein.

Suture sleeves are an adjustable, tubular reinforcement positioned over the outer lead insulation (Figure 3). They are designed to secure and protect the lead at the venous entry site after distal electrode fixation. Using suture sleeves optimizes lead longevity and reduces the possibility of structural damage caused by suturing directly over the lead body.

To move a suture sleeve, gently twist and pull it over the lead until it is in the desired position.

CAUTION: Do not suture directly over the lead body as this may cause structural damage. Use the suture sleeves to secure the lead lateral to the venous entry site.

Stylets

Stylets of varying stiffness are packaged with each lead. Stylets are also available as accessory items. A stylet inserted in the lead aids in positioning the lead tip in the heart. The stylet length is imprinted on the color-coded cap of the knob (Table 5). Also refer to “Inserting the Stylet” (Page 15) for more information.

Table 5. Stylets

	Stylet Length (cm)	Knob Color	Cap Color
Straight	59	Green=Soft or White=Firm	Yellow
	64		Green
	90		Orange

Stylet Guide

A stylet guide is packaged with the lead and is intended to ease insertion of a stylet into the pace/sense terminal of the lead (Figure 4).

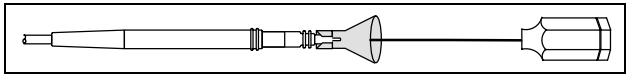


Figure 4. Using the stylet guide.

Vein Pick

The vein pick is a sterile, disposable, nontoxic, nonpyrogenic, plastic device designed to assist the physician during entry of the lead's electrode tip into the vein.

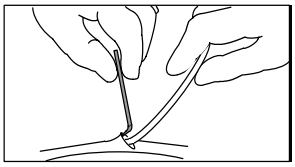


Figure 5. Using the vein pick.

To use the vein pick during a cutdown procedure, isolate and open the selected vein using an appropriate scalpel or scissors. Introduce the point of the vein pick via this incision into the lumen of the vein (Figure 5). With the point of the vein pick facing in the direction of the desired lead passage, gently raise and tilt the pick. Pass the lead under the vein pick and into the vein.

CAUTION: The vein pick is not intended either for puncturing the vein or for dissecting tissue during a cutdown procedure. Be sure that the vein pick does not puncture the silicone rubber insulation of the lead. This might allow body fluids to seep into the lead and could prevent proper lead function.

Lead Caps

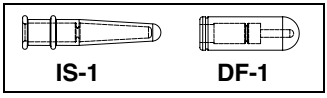


Figure 6. Use IS-1 lead caps on IS-1 terminals and DF-1 lead caps on DF-1 terminals.

The silicone rubber lead caps should be used to protect the lead terminals during the procedure (Figure 6). Lead caps may also be used to isolate or cap any lead terminal not inserted into the AICD pulse generator or AICD Y connector (if used). Placing a suture in the lead cap groove will secure the lead cap to the lead terminal.

Handling the Lead

Observe the following when handling the lead:

WARNING: Although pliable, the lead is not designed to tolerate excessive flexing, bending, or tension. This could cause structural weaknesses, conductor discontinuity, and/or lead dislodgment.

CAUTIONS:

- **Do not wipe or immerse the porous-tipped electrode in fluid**. Such treatment will reduce the

amount of steroid available when the lead is implanted.

- Chronic repositioning may adversely affect the lead's low-threshold performance because the steroid may be depleted.
- Do not attempt to alter the electrodes. Do not apply pressure to the tip of the electrode.
- The conductor insulation is silicone rubber, which can attract particulate matter and must always be protected from surface contamination.
- Mineral oil should never come in contact with a Guidant porous-tipped lead electrode. Mineral oil on the porous tip may inhibit tissue ingrowth and conduction.

Note: *Guidant suggests using sterile water if a lubricant is needed when coupling the lead with the VENTAK ECD cables, AICD pulse generator, or the AICD Y connector.*

IMPLANTATION

Inserting the Stylet

Choose a stylet according to the firmness desired. Remove the preinserted stylet before inserting a different one. Make sure the stylet is fully inserted in the lead prior to inserting the lead into the vein.

Gently curve the preferred stylet with any sterile, smooth-surfaced instrument (eg, 10- or 12-cc syringe barrel) (Figure 7) and carefully insert the stylet through the lumen of the connector. A sharp bend in the stylet can straighten as it passes through the lumen of the terminal pin. A gentle curve is less likely to straighten.

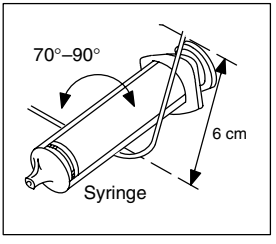


Figure 7. Curve the Stylet.

CAUTION: Do not bend the lead with a stylet in place. Bending the lead could damage the conductor and insulation material.

Note: *To optimize insertion into the lead, do not allow body fluids to come in contact with the stylet.*

Inserting the Lead

The lead may be inserted using one of the following methods:

- Via cutdown through the left or right cephalic vein.

  Only one incision (below the clavicle) is required to insert the lead through the cephalic vein. The endocardial lead is inserted into the right or left cephalic vein in the deltopectoral groove.

  The vein pick packaged with this lead can be used during a cutdown procedure to aid insertion of the lead into the vein. Before inserting the lead see the Accessory Options section for instructions on using the vein pick.

- Percutaneously or via cutdown through the subclavian vein or internal jugular vein—typically the left subclavian or right internal jugular vein.

  An 9 Fr subclavian introducer set is available from Guidant for use during percutaneous lead insertion.

CAUTION: When attempting to implant the lead via a subclavian puncture, do not insert the lead under the medial one-third region of the clavicle. Damage to the lead is possible if the lead is implanted in this manner. If implantation via the subclavian vein is desired, the lead must enter the subclavian vein near the lateral border of the first rib and must avoid penetrating the subclavius muscle. It is important to observe these implant precautions in order to avoid clavicle/first rib damage to the lead. It has been established in the literature that lead fracture can be caused by lead entrapment in such soft tissue structures as the subclavius muscle, costocoracoid ligament, or the costoclavicular ligament.[3]

Leads placed by percutaneous subclavian venipuncture should enter the subclavian vein where it passes over the first rib (rather than more medially) to avoid entrapment by the subclavius muscle or ligamentous structures associated with the narrow costoclavicular region.[4] Guidant recommends introducing the lead into the subclavian vein near the lateral border of the first rib.

The syringe should be positioned directly above and parallel to the axillary vein to reduce the chance that the needle will contact the axillary or subclavian arteries or the brachial

plexus. Use of fluoroscopy is helpful in locating the first rib and in guiding the needle. The steps below explain how to identify the skin entry point and define the course of the needle toward the subclavian vein where it crosses the first rib.

1. Referring to Figure 8, identify points St (sternal angle) and Cp (coracoid process).
2. Visually draw a line between St and Cp, and divide the segment into thirds. The needle should pierce the skin at the junction of the middle and lateral thirds, directly above the axillary vein (point Ax).
3. Place an index finger on the clavicle at the junction of the medial and middle thirds (point V), beneath which point the subclavian vein should be located.

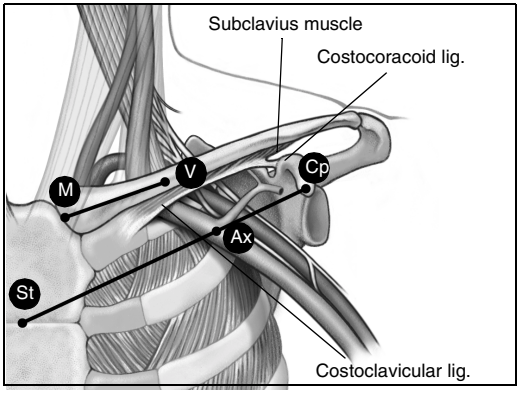


Figure 8. Landmarks identify the entry point for a percutaneous subclavian venipuncture.

4. Press a thumb against the index finger and project one or two centimeters below the clavicle to shield the subclavius muscle from the needle (when hypertrophy of the pectoralis muscle is apparent, the thumb should project about two centimeters below the clavicle because the subclavius muscle should be hypertrophied as well) (Figure 9).
5. Feel with the thumb the pressure from the passage of the needle through the superficial fascia; direct the needle deep into the tissues toward the subclavian vein and the underlying first rib. Fluoroscopic guidance will reduce the chance that the needle would pass below the first rib and into the lung.

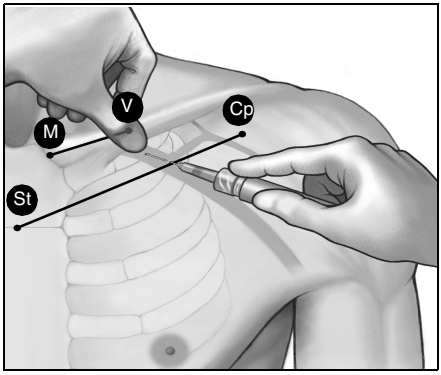


Figure 9. Location of thumb and needle entry.

CAUTION: When implanting the lead via a subclavian puncture, allow slack in the lead between the suture sleeve and the venous entry site. This will help minimize flexing at the suture sleeve and interaction with the clavicle/first rib region.

Positioning the Lead

Under fluoroscopy and with the stylet in the lead, advance the lead as far as possible to the apex of the right ventricle, where the porous tip electrode should be firmly wedged into the trabeculae (Figure 10 and Figure 11). Also verify under fluoroscopy that the distal spring electrode is situated in the right ventricle, below the tricuspid valve, and that the proximal spring electrode (ENDOTAK RELIANCE leads only) is situated in the superior vena cava and high right atrium. **Correct functioning of the lead depends on appropriate placement of the electrodes.**

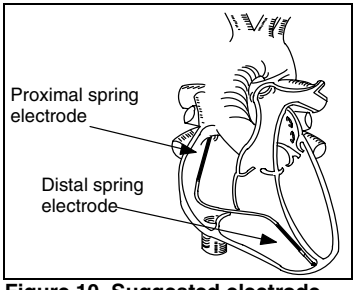


Figure 10. Suggested electrode position within the heart for ENDOTAK RELIANCE leads.

Note: *When the lead is used with an AICD pulse generator with pacing capability, position the distal tip in healthy myocardium in the apex of the heart.*

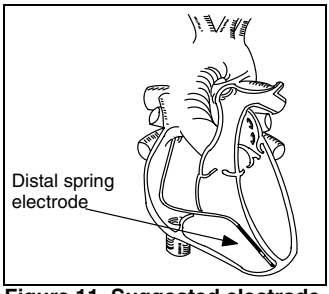


Figure 11. Suggested electrode position within the heart for ENDOTAK RELIANCE S leads.

WARNINGS:

- Take care to obtain appropriate electrode position. Failure to do so may result in higher defibrillation thresholds or may render the lead unable to defibrillate a patient whose tachyarrhythmia(s) might otherwise be convertible by an AICD system.
- In order to deliver defibrillation therapy, the single-coil ENDOTAK RELIANCE S lead must be implanted with a separate defibrillation electrode. Guidant recommends using the ENDOTAK RELIANCE S lead with a pectorally implanted AICD pulse generator that uses the metallic housing as a defibrillation electrode.

CAUTION: For patients with bipolar cardiac pacemakers, the lead pace/sense electrode (the porous tip and distal spring electrode) should be placed as far as possible from the pacemaker electrodes to avoid cross-sensing between the AICD pulse generator and the pacemaker.

Minimizing Pacemaker Interaction

To minimize potential interaction between a permanent pacemaker and an AICD pulse generator, consider the following.[5,6] After implanting the pacing leads, examine the signals from the pace/sense electrodes to ensure that minimal pacemaker artifacts are present. (Use a recording system that has a bandwidth of at least 2000 Hz to ensure that minimal pacemaker artifacts are present.)

- All of the patient's ventricular tachyarrhythmias and ventricular fibrillation should be induced while the AICD pulse generator is activated and the pacemaker is programmed to an asynchronous mode at maximum output. This should provide the greatest opportunity for inhibition of arrhythmia detection due to pacemaker artifacts. The pacing leads may have to be repositioned to eliminate artifacts.

- Since it is difficult to predict the relative magnitudes of pacemaker artifacts and various tachyarrhythmia electrograms that may occur chronically or during EP testing, it is important to reduce artifacts to the minimum.
- Consider programming the pacemaker to (1) the lowest amplitude allowable for safe capture in the chronic state, (2) the maximum sensitivity, and (3) the minimum cardiac rate acceptable for the patient. Also consider using pacemaker leads with close interelectrode spacing (eg, 1-2 cm).

Checking for Lead Stability

After positioning, partially withdraw the stylet past the most proximal electrode on the ENDOTAK RELIANCE lead or approximately 20 to 25 cm on the ENDOTAK RELIANCE S lead. Check the stability of the lead using fluoroscopy. If possible, have the patient cough or take several deep breaths. When electrode position is satisfactory, completely withdraw the stylet.

To provide temporary lead stabilization and hemostasis, ligate the vein and lead proximally and the vein distally to the venous entry site. Permanent lead stabilization and venous ligation will be performed following satisfactory electrogram evaluation and conversion testing.

Evaluating Lead Position

Verify electrical performance of the lead *before* attaching the lead to the pulse generator or Guidant's ECD and *after* allowing sufficient time for the effect of local tissue trauma to subside. The use of radiography or fluoroscopy during the operation may help ensure lead position and integrity. If testing results are unsatisfactory, lead system repositioning or replacement may be required.

Taking Baseline Measurements

Connect the terminal pins to a pacing system analyzer (PSA) and evaluate the placement by determining the following:

- R-wave amplitude
- Pacing threshold
- Pacing lead impedance

Note that the pulse generator measurements may not exactly correlate to the PSA measurements due to signal filtering. Baseline measurements should fall within the recommended values listed in Table 6.

Table 6. Recommended Lead Signal Parameters[a]

Signal Type	Amplitude [a, b, c]	Duration [a, b, c]	Pacing Threshold [d]	Impedance
Pacing/ Sensing	≥5 mV	<100 ms	≤1.5 V	450–1800 Ω
Defibrillation	≥1 mV	<150 ms	NA	20–80 Ω

a. Measured approximately 10 minutes after placement.
b. This measurement is not inclusive of current injury.
c. In normal sinus rhythm.
d. Pulse width setting at 0.5 ms.

Lower intrinsic potentials, longer durations, and higher pacing thresholds may indicate lead placement in ischemic or scarred tissue. Because signal quality may deteriorate, reposition the lead if necessary to obtain a signal with the largest possible amplitude, shortest duration, and lowest pacing threshold.

CAUTION: R-wave amplitudes of less than the recommended value can cause inaccurate rate counting in the chronic state, possibly resulting in failure to sense a tachyarrhythmia or misdiagnosis of a normal rhythm as abnormal. Signal durations that exceed the programmed refractory period of the AICD pulse generator can cause inaccurate cardiac rate determination or inappropriate high-voltage shock delivery or both.

If the measurements do not conform to these values, reinsert the stylet and reposition the lead using the positioning procedures previously discussed. Verify that measurements fall within the recommended values. If testing results are unsatisfactory, further lead system repositioning or replacement may be required.

Electrical Performance

Make the lead connections and evaluate the lead signals using either the pulse generator or a Guidant ECD.

WARNING: When connecting the lead to ECD cables and/or the AICD pulse generator, it is very important that proper connections are made. **Damage to the heart could result if a high-voltage defibrillating pulse were to be delivered through the rate-sensing porous tip electrode.**

Note: *Prior to connecting the cardioversion/defibrillating leads to the ECD, ensure the ECD's output circuitry is disabled and any electrocautery equipment is turned off and*

unplugged. Consult the ECD user's manual for directions concerning connecting the ECD cables to the ECD and the ECD to a chart recorder.

Evaluating with the Pulse Generator

Connect the terminal pins to the pulse generator and place the AICD pulse generator into the AICD implant pocket as indicated in the AICD physician's manual. Also, refer to "Connection to a Pulse Generator" (Page 27) for more information.

Evaluate the lead signals by viewing the real-time EGM. The signal from the implanted lead should be continuous and without artifact, similar to a body-surface ECG. A discontinuous signal may indicate a lead fracture or otherwise damaged lead, or an insulation break that would necessitate lead replacement. Inadequate signals may result in failure of the AICD system to detect an arrhythmia or in unnecessary delivery of therapy.

Evaluating with the ECD

Connect the pace/sense lead terminal pin to the sterile bipolar cable. Connect the defibrillation lead terminal pins to the high-voltage cable. Then connect the bipolar and high-voltage cables to the respective connectors on the Guidant ECD.

Evaluate the lead signals using the Programmer/Recorder/Monitor (PRM) programming system or an external strip chart recorder. As seen on the strip chart recorder, the signal from the implanted lead should be continuous and without artifact, similar to a body-surface ECG. A discontinuous signal may indicate a lead fracture or otherwise damaged lead, or an insulation break that would necessitate lead replacement. Inadequate signals may result in failure of the AICD system to detect an arrhythmia or in unnecessary delivery of therapy.

CAUTIONS:

- Guidant ECDs are synchronized external cardioverter defibrillators capable of delivering high-energy pulses (up to 40 J) to the patient. **Be thoroughly familiar with ECD operation prior to connecting the lead to the ECD.** Never use the ECD without a standard external defibrillator immediately available as a backup.
- Remove the stylet from the lead before connecting the lead to the ECD bipolar cable. A stylet left in the lead could (1) cause false electrical readings, (2) cause lead perforation, or (3) prevent use of a

new stylet should relocation of the lead be necessary.

Conversion Testing

After obtaining acceptable signals, use the AICD pulse generator or ECD to demonstrate ability to reliably convert ventricular fibrillation (VF) and, when appropriate to the patient, ventricular tachycardias. The ECD can substitute for an AICD pulse generator during conversion testing. This testing involves inducing arrhythmias and shocking the patient with high-voltage pulses delivered from the AICD pulse generator or ECD, through the defibrillating electrodes of the lead, to the heart.

CAUTION: Following an unsuccessful high-energy shock, miscounting of cardiac rate, delayed detection, or nondetection due to low amplitude VF signals, it may be necessary to use a separate rate-counting electrode system. If a separate pace/sense electrode system (such as Guidant Model 4055 Sweet Picotip™ Rx) is used, its interelectrode spacing must be no greater than 1-2 cm because greater separation may cause the signal from the leads to exceed the refractory period of the AICD pulse generator, resulting in oversensing in normal rhythm, or undersensing in polymorphic rhythm.

In addition, a wide pace/sense electrode separation may contribute to oversensing by introducing a large repolarization signal (T-wave), thereby causing false fulfillment of the rate criteria.

Reliable conversion of VF should be demonstrated at an energy level less than the maximum energy setting of the pulse generator. Guidant recommends that multiple induction conversion tests of VF be performed to determine conversion reliability and the patient's defibrillation threshold (DFT). It is a matter of clinical judgment as to what constitutes a demonstration of reliable conversion. Since the result of any single test is subject to statistical variation, a one-time conversion of a rhythm disturbance at a particular energy level does not necessarily predict future conversion energy levels. Refer to the applicable AICD physician's manual for conversion testing guidelines.

Weigh the probability of reliable conversion in the ambulatory state against the availability of AICD energy settings and the patient's ability to tolerate multiple arrhythmia inductions.

If a patient's arrhythmia(s) cannot be reliably converted with an ENDOTAK RELIANCE or ENDOTAK RELIANCE S lead, supplementary implantation of an ENDOTAK SQ lead array or an alternate lead system will require additional conversion testing. Refer to the ENDOTAK SQ lead physician's manuals for instructions concerning auxiliary use of these leads with the ENDOTAK RELIANCE or ENDOTAK RELIANCE S lead.

CAUTION: An ENDOTAK lead system may increase the energy required to cardiovert/defibrillate the heart with transthoracic paddles. Care should be taken **not** to place the external defibrillator paddles directly over the ENDOTAK SQ lead.

WARNING: Use of any component of the ENDOTAK lead system to assist in delivery of external-source rescue shocks could cause extensive tissue damage.

The decision to implant any AICD lead system in any configuration should be based on demonstration of adequate safety margins at the programmed shock energy as determined by DFT and cardioversion energy requirement (CER) testing. Refer to the applicable AICD physician's manual for DFT and CER testing requirements.

Clinical study indicates that a programmed safety margin of 9–10 J above the patient's DFT was used in the majority of patients. If a 9–10 J safety margin cannot be obtained, consider placing an additional defibrillation lead.

Note: *If, after prolonged and repeated inductions of VF, a thoracotomy is to be performed, consider performing it at a later date.*

If using an ECD and after arrhythmia testing has been completed, turn off the ECD and disconnect the ECD cables per instructions in the ECD user's manual.

Securing the Lead

After the electrodes are satisfactorily positioned and conversion testing has been performed, secure the lead to the vein to achieve permanent hemostasis and lead stabilization. Suture sleeve tie-down techniques can vary with the lead insertion technique used. Securing the lead will provide permanent hemostasis and lead stabilization.

Percutaneous Implant Technique

1. Peel back the introducer sheath and slide the suture sleeve deep into the tissue (Figure 12).

2. Using both grooves, ligate the suture sleeve to the lead.
3. Next, secure the sleeve and lead to the fascia.

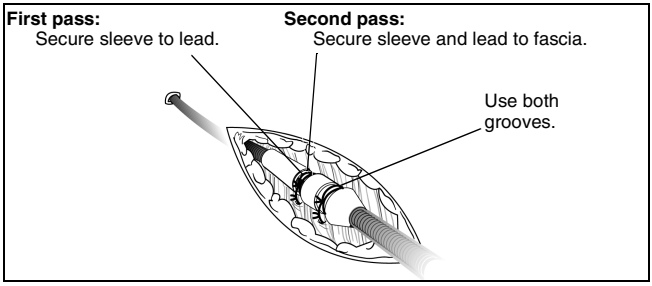


Figure 12. Using the sleeve with the percutaneous implant technique.

4. Check the suture sleeve after tie-down to demonstrate stability and lack of slippage by grasping the suture sleeve with fingers and trying to move the lead in either direction.

Venous Cut-Down Technique

1. Slide the suture sleeve into the vein past the distal pre-formed groove. Ligate the vein around the suture sleeve to obtain hemostasis. Next, using the same groove, secure the lead and vein to the adjacent fascia (Figure 13).

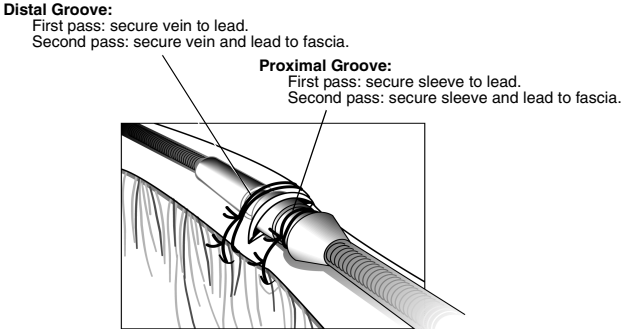

Distal Groove:
First pass: secure vein to lead.
Second pass: secure vein and lead to fascia.
Proximal Groove:
First pass: secure sleeve to lead.
Second pass: secure sleeve and lead to fascia.

Figure 13. Using the sleeve with the venous cutdown technique.

2. Using the proximal pre-formed groove, secure the sleeve to the lead. Using the same groove, secure the sleeve and lead to the adjacent fascia.

3. Check the suture sleeve after tie-down to demonstrate stability and lack of slippage by grasping the suture sleeve with fingers and trying to move the lead in either direction.

Note: *If venous entry is made using a Guidant lead introducer, ligate the lead to the adjacent fascia using the suture sleeve to prevent lead movement.*

Models 0129 and 0149 Only–Abdominal implants

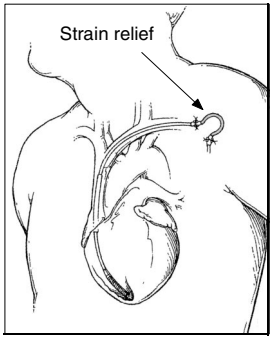


Figure 14. Position and shape of the strain relief loop (Models 0129 and 0149 only).

Allow slack on the lead for strain relief on the lateral side of the suture sleeve near the venous entry site when securing the leads to body tissue (Figure 14). This will prevent lead dislodgment caused by the weight of the pulse generator or upper extremity movement.

Note: *When implanting the lead via a subclavian puncture, allow slack in the lead between the distal suture sleeve and the venous entry site. This will help minimize flexing at the suture sleeve and interaction with the clavicle/first rib region.*

WARNING: Do not kink, twist, or braid the lead terminal with other leads as doing so could cause lead insulation abrasion damage.

CAUTIONS:

- When ligating the vein, avoid too tight a stricture. A tight stricture might damage the silicone rubber insulation or sever the vein. Avoid dislodging the electrode tip during the stabilization procedure.
- Do not remove or cut the suture sleeves from the lead as it may cause lead damage.

Tunneling the Lead to the Abdominal Pocket

A short terminal leg (STL) tunneling tool is recommended for use with this lead if the AICD pulse generator is implanted in the abdomen. Tunnel the lead subcutaneously from the chest area to the abdominal AICD implant pocket. If the tunneling procedure must be delayed, cap the lead terminal pin and

form a temporary pocket for the coiled lead. Capping the terminal pin protects it and prevents body fluids from entering the lumen of the lead, which may cause lead malfunction.

Note: *When using a Guidant lead tunneler, do not cap the leads.*

CAUTIONS:

- Tunnel the lead from the chest area to the pulse generator implant site. Never tunnel the lead from the pulse generator implant site to the chest area. This could damage the electrodes and/or lead body by permanently stretching the lead.
- When tunneling the lead take precautions not to place excessive tension on the lead. This can cause structural weaknesses and/or conductor discontinuity.
- After tunneling, reevaluate the lead to verify that no significant change in lead signals or damage to the lead has occurred during the tunneling procedure.

Reattach the lead terminals to the AICD pulse generator or ECD cables. If the measurements are unacceptable, check the electrical connections. A discontinuous or abnormal signal may indicate dislodgment, a loose connection, or lead damage. If necessary, reposition the lead electrodes until acceptable values are obtained. To reposition the lead, carefully withdraw the tunneled portion back to the venous entry site. Release the permanent ligatures and reposition the lead using procedures previously discussed.

Connection to a Pulse Generator

Consult the AICD physician's manual for directions concerning connecting the lead terminals to the pulse generator.

Verify the stylet is removed prior to connecting the lead to the pulse generator.

CAUTION: Insert the IS-1 lead terminal straight into the lead port. Do not bend the lead near the lead-header interface. Improper insertion can cause insulation damage near the terminal ring that could result in lead damage.

Notes:

- *If necessary, lubricate the lead terminal sparingly with sterile water to make insertion easier.*

- *If the lead terminal pin will not be connected to an AICD pulse generator at the time of lead implantation, the lead connector **must** be capped before closing the pocket incision. Place a suture around the lead cap to keep it in place.*

The pace/sense terminal is inserted into the AICD lead port identified as the ventricular pacing/sensing port. The defibrillating terminals are inserted into the AICD lead ports identified as defibrillating, maintaining the polarity and electrode configuration determined during DFT testing.

Giving consideration to patient anatomy and pulse generator size and motion, gently coil any excess lead and place adjacent to the pulse generator. It is important to place the lead into the pocket in a manner that minimizes lead tension, twisting, sharp angles, and/or pressure.

POST-IMPLANT EVALUATION

Follow-Up Testing

Perform follow-up evaluation as recommended in the applicable AICD pulse generator physician's manual.

CAUTION: For some patients, lead performance at implant may not predict performance in the chronic state. **Therefore, Guidant strongly recommends that post-implant follow-up EP testing be performed before the patient is discharged from the hospital.** This testing should include at least one arrhythmia induction/conversion test of ventricular fibrillation.

In addition to the pulse generator follow-up instructions, use beeping tones to evaluate pacing/sensing integrity. If programmed accordingly, placing and holding a magnet over an active implanted pulse generator elicits tones synchronous with the R-wave of the pace/sense electrodes. If a problem exists with the pace/sense electrodes or their interface with the pulse generator, it may be revealed by evaluating the beeping tones of the device. Refer to the applicable AICD system manual for specific instructions.

Explantation

Return all explanted leads to Guidant. Examination of explanted leads may provide information for continued improvement in system reliability. Use a Guidant Returned Product Kit to properly package the lead and complete an Observation/Complication/Out-of-Service Report form. Send

the form and kit to Guidant at the address on the back of this manual.

Note: *Disposal of explanted devices is subject to local, state, and federal regulations. Contact your Guidant representative or call Guidant at 1-800-CARDIAC for a Returned Product Kit.*

REFERENCES

1. DF-1 refers to the international standard ISO 11318:1993.
2. IS-1 refers to the international standard ISO 5841.3:1992.
3. Magney JE, et al. Anatomical mechanisms explaining damage to pacemaker leads, defibrillator leads, and failure of central venous catheters adjacent to the sternoclavicular joint. *PACE.* 1993;16:445-457.
4. Magney JE, et al. A new approach to percutaneous subclavian venipuncture to avoid lead fracture or central venous catheter occlusion. *PACE.* 1993;16:2133-2142.
5. Epstein AE, et al. Combined automatic implantable cardioverter-defibrillator and pacemaker systems: implantation techniques and follow-up. *JACC.* 1989;13:121-131.
6. Calkins H, et al. Clinical interactions between pacemakers and automatic implantable cardioverter-defibrillators. *JACC.* 1990;16:666-673.

SPECIFICATIONS (Nominal)

	ENDOTAK RELIANCE S	ENDOTAK RELIANCE
Models	0127/0128/0129	0147/0148/0149
Length	0127–59 cm, yellow 0128–64 cm, green 0129–90 cm, orange	0147–59 cm, yellow 0148–64 cm, green 0149–90 cm, orange
Terminal sizes	(1) IS-1 bipolar, (1) DF-1	(1) IS-1 bipolar, (2) DF-1
Compatibility	Guidant AICD pulse generators, ENDOTAK SQ array leads, and AICD Y connector	
Recommended lead introducer size[a]	9 Fr	9 Fr
Tip to proximal spring electrode length	NA	18 cm
Diameter:		
Isodiametric lead body	2.7 mm	2.7 mm
Coil electrode	2.7 mm	2.7 mm
Porous tip base	2.0 mm	2.0 mm
Active surface area:		
Distal spring electrode	450 mm^2	450 mm^2
Proximal electrode	NA	660 mm^2
Active tip electrode	2.0 mm^2	2.0 mm^2
Material:		
External insulation	Silicone rubber	
DF-1 terminal pin	Titanium	
IS-1 terminal pin	Stainless steel	
Pace/Sense conductor	MP35N nickel-cobalt alloy, PTFE coated	
Shocking conductor	Drawn brazed strand cable, PTFE coated	
Tip electrode	Platinum iridium	
Steroid	Approximately 1.0 mg dexamethasone sodium phosphate	

a. Implants using the retained guide wire technique may require a 10.5 Fr introducer.

GUIDANT

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